

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 11-13-59. Default—destruction.

**DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE
HAD BEEN ISSUED**

DRUG FOR VETERINARY USE

6087. Entero-Sol Powder. (F.D.C. No. 43323. S. No. 71-708 P.)

QUANTITY: 10 cases, 12 btl. each, at Gainesville, Ga.

SHIPPED: 5-25-59, from Vineland, N.J., by Eastern Laboratories, Inc.

LABEL IN PART: (Btl.) "Rollins Entero-Sol Powder For the treatment of Enteritis, Air-Sac, Colds and Blue Comb in Chickens and Turkeys * * * Contents 156 Gms. Each Pound Contains: 24,000,000 units of Penicillin G. Potassium 24,000 mg. of Dihydrostreptomycin Base as sulphate, and 3,600 mg. of Menadione Sodium Bisulfite (Synthetic Vitamin K) In addition each pound contains: * * * Manufactured for Ben C. Rollins Company 602 Grove Street, Gainesville, Georgia."

LIBELED: 8-4-59, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an adequate and effective treatment for colds in chickens and turkeys; and 502(1)—the article consisted in part of penicillin and dihydrostreptomycin and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 9-23-59. Default—destruction.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6088. Dextro-amphetamine sulfate tablets and amphetamine sulfate tablets. (F.D.C. No. 43391. S. Nos. 73-809/10 P.)

QUANTITY: 5 1,000-tablet btl. at Bay Saint Louis, Miss.

SHIPPED: Prior to 7-7-59, from outside the State of Mississippi.

RESULTS OF INVESTIGATION: The bottles were unlabeled. Analysis showed that 3 bottles contained *dextro-amphetamine sulfate tablets* and 2 bottles contained *amphetamine sulfate tablets*.

LIBELED: 7-13-59, S. Dist. Miss.

CHARGE: 502(b)—while held for sale, the article failed to bear (1) a label containing the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of count; 502(e) (1)—the label failed to bear the common or usual name of the drug; 502(f) (1)—the label of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was in possession of a person or persons not authorized to dispense a prescription drug; and 503(b) (4)—the label of the article failed to bear the statement "Caution—Federal law prohibits dispensing without prescription."

DISPOSITION: 8-18-59. Default—destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

DRUGS FOR HUMAN USE*

6089. Napier's 14 & 10 Vitamins-Minerals tablets, Napier's Special Formula tablets, Napier's Inhalant & Rubbing Oil, and Napier's Family Salve.
(F.D.C. No. 43099. S. Nos. 25-277/80 P.)

INFORMATION FILED: 9-14-59, N. Dist. Iowa, against Don A. Napier, Tahlequah, Okla.

ALLEGED VIOLATION: On 9-11-58, the defendant, in the course of a sales talk at the Clay County Fair, Spencer, Iowa, made oral representations holding out *Napier's 14 & 10 Vitamins-Minerals tablets* (count 1), *Napier's Special Formula tablets* (count 3), *Napier's Inhalant & Rubbing Oil* (count 5), and *Napier's Family Salve* (count 6), as treatments for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded while held for sale in violation of 502(f) (1).

The information alleged also that the defendant caused *Napier's 14 & 10 Vitamins-Minerals tablets* (count 2) and *Napier's Special Formula tablets* (count 4) to be accompanied by labeling, namely, the booklets and leaflets referred to below, which acts resulted in the articles being misbranded while held for sale in violation of 502(a).

LABEL IN PART: "NAPIER'S 14 & 10 (Improved) VITAMINS-MINERALS 60 Tablets—30 day supply Prepared for CHIEF D. A. NAPIER R.R. #3 · Tahlequah, Okla."; "100 Tablets NAPIER'S Special Formula E.P. A high potency dietary supplement furnishing a wide range of vitamins and minerals Distributed by CHIEF D. A. NAPIER R.R. #3 · Tahlequah, Okla."; NAPIER'S Inhalant & Rubbing Oil. Relieve Symptoms of COLDS by inhaling also use as a RUBBING OIL for soreness in the body due to COLDS AND FATIGUE Active Ingredients: Eucalyptus Oil, Menthol, Peppermint Oil, Thymol, Camphor Contents 1 Fl. Oz. CHIEF D. A. NAPIER R.R. 3 Tahlequah, Okla."; and "CONTENTS 2 Fl. Ozs. NAPIER'S FAMILY SALVE. Active Ingredients: Methyl Salicylate, Oil Pine Tar and Balsam Peru in a Petrolatum base. DIRECTIONS: CHIEF D. A. NAPIER R.R. 3 TAHLEQUAH, OKLA."

ACCOMPANYING LABELING: Booklet entitled "Napier's Health Book" and a leaflet entitled "How vitamins and minerals help the whole family."

CHARGE: 502(a)—the labeling which accompanied the *Napier's 14 & 10 Vitamins-Minerals tablets* and *Napier's Special Formula tablets* contained false and misleading representations that such articles were adequate and effective to insure radiant health, and to prevent and treat practically all diseases and pathological conditions of man, including tuberculosis, heart disease, liver and kidney disorders, gout, jaundice, skin diseases, indigestion, sexual weakness or impotence, mental deficiency, diabetes, catarrh, sores that do not heal, arthritis, rheumatism, chronic bronchitis, and sclerosis of the liver; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Napier's 14 & 10 Vitamins-Minerals tablets*) in the treatment of arthritis, rheumatism, high blood pressure, improving eyesight, and insuring good health generally; (*Napier's Special Formula tablets*) for restoring lost manhood, improving

*See also Nos. 6082-6084, 6088.

sexual powers and for sexual rejuvenation; (*Napier's Inhalant & Rubbing Oil*) for the treatment of sinus trouble, catarrh, asthma, hay fever, grippe, earache, chilblains, and pain in the neck, back, or leg; and (*Napier's Family Salve*) in the treatment of all kinds of burns, scalds, eczema, impetigo, skin rashes, poison oak, poison ivy, ringworm, itching, bleeding, blind or protruding hemorrhoids, and varicose vein sores.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 10-27-59.

On 10-29-59, the jury returned a verdict of guilty on counts 1, 3, 5, and 6, and not guilty on counts 2 and 4. On 12-17-59, the defendant was sentenced to 1 year imprisonment, which was suspended, and the defendant was placed on probation for 4 years.

6090. Bath minerals. (F.D.C. No. 43510. S. No. 51-468 P.)

QUANTITY: 30 3-lb. bags at Milwaukee, Wis.

SHIPPED: 5-14-59, from Soap Lake, Wash.

LABEL IN PART: (Sticker on bags) "Mother Nature Co. 'World's Most Miraculous Health Products' 1300 No. 12th St. * * * Milwaukee, Wis." and (rubber stamp on bags) "H. H. Wolfgram, 1300 N. 12th Street, Milwaukee 5, Wis. Mother Nature Co."

ACCOMPANYING LABELING: Circulars entitled "Now You Can Take These Famous Mother Nature Baths."

RESULTS OF INVESTIGATION: The article was repacked and labeled by the dealer from bulk stock shipped as described above. The circulars were printed on order of the dealer.

LIBELED: 8-28-59, E. Dist. Wis.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for eliminating objectionable body odor; brightening the eyes; building up resistance to disease; inducing sound refreshing sleep; rheumatism; arthritis; neuritis; gout; high blood pressure; diabetes; gangrene; nervous disorders; circulatory ailments; general skin troubles; foot troubles, ulcers; Buerger's disease; skin infections; female disorders; varicose open sores; migrating phlebitis; osteomyelitis; and stomach and intestinal disorders; 502(b)(2)—the article failed to bear a label containing an accurate statement of the quantity of its contents; 502(e)(2)—the label of the article failed to bear the common or usual name of each of the active ingredients contained therein; and 502(f)(2)—the article was offered for vaginal douching and its labeling failed to bear a warning that it should not be used more than twice weekly unless otherwise directed by a physician.

DISPOSITION: 11-24-59. Default—destruction.

6091. Vydagen laxative compound. (F.D.C. No. 43530. S. No. 65-875 P.)

QUANTITY: 10 ctns., containing a total of 1,144 cans, at Hamburg, N.Y.

SHIPPED: 7-29-59, from Irvington, N.J.

LABEL IN PART: (Can) "(Vydagen A Supplementary Laxative Compound containing no Chemical or habit forming Drugs * * * Ingredients: Agar Agar, Indian Plantago, Ovata Seed, Dextrine, Lactose * * * Net Weight 5 Oz. Vydagen Products, 239 Munn Avenue, Irvington, N.J.)"